



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20196

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

25/MAR/2014

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 83100-GL

Name of Pesticide Product: Emamectin Benzoate 4% SL  
EPA Reg. No.: 83100-GL  
DP Barcode: D415805  
Decision No.: 483360  
Action Code: R310  
PC Code: 122806 (emamectin benzoate)

From: Eugenia McAndrew, Biologist  
Technical Review Branch  
Registration Division (7505P)

*E. McAndrew*

*M. Hashi*  
TOXICOLOGIST/RD

To: Thomas Harris, RM Team 07  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Applicant: Rotam Agrochemical Company Limited  
c/o Wagner Regulatory Associates  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, DE 19707

FORMULATION FROM LABEL:

Active Ingredient(s):  
Emamectin benzoate

% by wt.  
4.0

Other Ingredient(s):

96.0  
Total: 100.0%

**ACTION REQUESTED:** The Risk Manager requests a review of six acute toxicity studies submitted to support the registration of EPA File Symbol 83100-GL.

**BACKGROUND:** Rotam Agrochemical Company Limited has submitted six acute toxicity studies with MRIDs 492196-03 to -08 for Emamectin Benzoate 4% SL, EPA File Symbol 83100-GL. The submission includes a basic CSF which must be reviewed and accepted by the TRB Product Chemistry Team.

**GLP:** Yes

**DEVIATIONS:** None

**LABELING:**

**PRODUCT ID #:** 083100-00035

**PRODUCT NAME:** Emamectin Benzoate 4% SL

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]\*

\*[Protective eyewear may be specified, if appropriate.]

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

## DATA EVALUATION RECORD

**Product Reg. No.:** 83100-GL

**Product Name:** Emamectin Benzoate 4% SL

<b>1. DP BARCODE:</b> 415805				
<b>2. PC CODE:</b> 122806				
<b>3. CURRENT DATE:</b> March 25, 2014				
<b>4. TEST MATERIAL:</b> Emamectin Benzoate 4% SL (Batch # 20121102001; 4.09% emamectin benzoate; pH 5.9; density 0.9608 g/mL; blue liquid; administered as received)				
<b>Study/Species/Lab Study # /Date</b>	<b>MRID</b>	<b>Results</b>	<b>Tox Cat</b>	<b>Core Grade</b>
Acute oral toxicity / rat International Institute of Biotechnology and Toxicology India Study #12476/January 31, 2013 OCSPP 870.1100; OECD 425	49219603	LD <sub>50</sub> Females = 1098 mg/kg (95% CI 550 to 2000 mg/kg) 8 animals tested at 175, 550 or 2000 mg/kg  Mortality: 4/4 at 2000 mg/kg  Clinical signs:  175 (1 animal) and 550 (3 animals) mg/kg: all animals survived; no clinical signs; body weight gains; no gross abnormalities at necropsy  2000 mg/kg (4 animals) 4/4 animals died by day 2 with dullness, catalepsy, lacrimation and salivation noted prior to death; no abnormalities noted at necropsy	III	A
Acute dermal toxicity / rat International Institute of Biotechnology and Toxicology India Study #12477/January 31, 2013 OCSPP 870.1200; OECD 402	49219604	LD <sub>50</sub> > 2000 mg/kg (both sexes) all animals survived; no clinical signs; body weight gains; no gross abnormalities at necropsy	III	A

Acute inhalation toxicity / rat International Institute of Biotechnology and Toxicology India Study #12481/January 28, 2013 OCSPP 870.1300; OECD 403	49219605	LC <sub>50</sub> > 4.65 mg/L (both sexes) MMAD: 2.43 µm GSD: 1.87 6 animals tested at limit dose (OECD Guideline 403) Mortality: 1 female died on day 10 clinical signs: dullness was observed in all animals during exposure; change of body coat color, dullness, respiratory distress, nasal irritation were noted in all animals post exposure and tremors were noted in 2 animals with recovery by day 10; all rats lost weight through day 3; by day 14 all rats had gained weight but only 1 rat exceeded original weight; no gross abnormalities at necropsy	IV	A
Primary eye irritation / rabbit International Institute of Biotechnology and Toxicology India Study #12479/January 31, 2013 OCSPP 870.2400; OECD 405	49219606	3 females tested pH 6.2 Score of 1 for conjunctival redness and chemosis at 1 hr increasing to scores of 2-3 at 24 and 48 hrs in all eyes; no positive scores for conjunctivitis by day 5; corneal opacity in 2/3 eyes from 48 hrs through day 6 resolving by day 7; all eyes free of irritation by day 7	III	A
Primary dermal irritation / rabbit Biotechnology and Toxicology India Study #12478/January 31, 2013 OCSPP 870.2500; OECD 404	49219607	PDI = 0.0 pH 6.2 3 females tested No irritation observed	IV	A
Dermal sensitization / guinea pig Biotechnology and Toxicology India Study #12480/January 31, 2013 OCSPP 870.2600; OECD 406	49219608	Is <i>not</i> a sensitizer Appropriate positive control provided	--	A

**Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap**